


12/18/96-00658

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
841 Chestnut Building  
Philadelphia, Pennsylvania 19107

**SUBJECT:** Norfolk Naval Base  
Human Health Risk Assessment Assumptions  
Sites 2, 5, and the Camp Allen Salvage Yard

**DATE:** 12/18/96

**FROM:** Nancy Rios Jafolla, Toxicologist   
Technical Support Section (3HW41)

**TO:** Harry Harbold, RPM  
Federal Facilities Branch (3HW50)

I have reviewed the subject document for toxicological accuracy. I have the following comments to offer for further consideration:

1. The expected land uses for the sites need to be defined further.
2. Site-specific contaminant levels for background samples can be compared to site-specific on-site contaminant levels to further characterize the risk at the site. A site-related contaminant that is presently on-site at levels above background levels is eliminated from the risk assessment only at the discretion of the risk manager. The on-site contaminant levels should be compared to the background levels (site-specific) statistically. The population means for the two data sets can be compared using a Student T-test ( $\alpha = 0.05$  described in Zar 1974) to determine significant differences between the two population means for normally distributed populations with equal variances. If the distribution is not described by a normal distribution, the Mann-Whitney non-parametric test described in Gilbert 1987 can be used. The risk level at the background level should be presented in the document along with the on-site risk level and the remediation risk level (RL) to assist in determining the most protective and cost effective remedial action for the site. Only at that time can the contaminant be eliminated based on background.
3. The Regional Guidance on Monte Carlo should be followed to calculate Monte Carlo risk estimates (see Attachment).
4. The Regional Soil Dermal Guidance should be followed to calculate dermal risk estimates (see Attachment).
5. The tables describing the exposure scenarios at the sites need to be revised to reflect the appropriate exposure scenarios being considered at the sites based on the appropriate land uses.

6. Exposure to subsurface soil should be considered for the construction workers as well as future residents and industrial workers, if construction and excavation of site subsurface soil are anticipated. The risks for surface soil (current surface soil, and surface soil derived from subsurface soil excavation and used as clean fill) should not be added together for the future resident and industrial worker, since both risk estimates are based on the same exposure media (i.e., surface soil). These risk estimates should be characterized separately in the risk assessment because the exposure is not expected to occur simultaneously for these receptors. Note, however, that one of the risk estimates for surface soil (either from current surface soil or from subsurface soil assumed to be surface soil) should be added to the total risk for the site.
7. The following changes in exposure parameters should be considered in the risk assessment:

**A. Exposure Pathway:**

**Trespasser**

Exposure time (hours/event)- 2 (1- for the Pesticides site)

Exposure frequency (days/year)- 52

Ingestion rate (mg/day)- 100 (soil and sediment)

Age- 6-16 years

Body weight-36 kg

Exposure duration- 10 years

**Workers**

Inhalation rate (m<sup>3</sup>/hr) for the Construction Worker- 1.7

Exposure frequency for the Future Park Maintenance Worker (days/year) - 180

[Central Tendency (CT) the same]

Ingestion rate (mg/day) for the Future Utility Workers- 480 (CT the same)

**Recreational**

Exposure frequency (days/year)-100

**B. Exposure Route:**

**Dermal Route/Skin Surface Area:**

Resident Child: \*1981 cm<sup>2</sup>, 7926 cm<sup>2</sup> (total body)

Resident Adult: \*5800 cm<sup>2</sup>, 20,000 cm<sup>2</sup> (total body)

Trespasser Youth: 11-12 years, 3578 cm<sup>2</sup>

Industrial Worker: 5300 cm<sup>2</sup> (3230 cm<sup>2</sup> CT)

\*This number was derived by multiplying the total body surface area by 25% to account for soil contact scenarios outside (e.g., hands, arms, legs, neck and head). See Dermal Guidance.

### **C. Media Specific:**

#### **Surface Soil and Sediment**

Fraction of Contaminated Soil Ingested (unitless)- 1

Volatilization rate (m<sup>3</sup>/kg)- see Soil Screening Guidance for derivation

(Note: It is not necessary to calculate an inhalation risk for the trespasser scenario and for the surface water recreational exposure scenario)

#### **Ground Water**

The Foster and Chrostowski Shower Model (1987) should be used to calculate the air contaminant concentration in the shower stall.

Further consideration should be given to ground water exposures at the Camp Allen Savage Yard.

#### **Surface Water**

A future offsite qualitative recreational risk assessment should be done for the Slag Pile site.

I have no further comments at this time. Please let me know if you need further assistance.

#### **Attachments**

cc: EJohnson (3HW41) w/o attachments

Region III  
Technical Guidance Manual  
Risk Assessment

## Assessing Dermal Exposure from Soil

EPA Contact: Jennifer Hubbard



EPA  
Region III

Hazardous Waste Management Division  
Office of Superfund Programs  
December 1995

Dermal absorption from soil is one of the routes of exposure that may be addressed during risk assessment at Superfund sites. One factor necessary to estimate dose, and therefore risk, via this route is the absorption factor of a chemical from soil. This document is intended to provide default assumptions for this factor in the assessment of dermal soil exposure.

### ASSESSING DERMAL CONTACT WITH SOIL; EXISTING GUIDANCE

Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A) ("RAGS"; EPA, 1989) presents an equation used to estimate exposure from dermal contact with soil:

$$AD = \frac{CS \times CF \times SA \times AF \times ABS \times EF \times ED}{BW \times AT}$$

Where:

AD = Absorbed dose (mg/kg/day)  
CS = Chemical concentration in soil (mg/kg)  
CF = Conversion factor ( $10^{-6}$  kg/mg)  
SA = Skin surface area available for contact ( $\text{cm}^2/\text{event}$ )  
AF = Soil-to-skin adherence factor ( $\text{mg}/\text{cm}^2$ )  
ABS = Absorption factor (unitless)  
EF = Exposure frequency (events/year)  
ED = Exposure duration (years)  
BW = Body weight (kg)  
AT = Averaging time (period over which exposure is averaged-days)

(RAGS, Exhibit 6-15)

RAGS then states: "Absorption factors (ABS) are used to reflect the desorption of the chemical from soil and the absorption of the chemical across the skin and into the bloodstream. Consult the open literature for

information on chemical-specific absorption factors. In the absence of chemical-specific information, use conservative assumptions to estimate ABS." The use of conservative assumptions is appropriate when determining Reasonable Maximum Exposure (RME), and reflects EPA's policy that protection of human health should be ensured.

Assessment of dermal exposure is important for a complete risk assessment. This document summarizes chemical-specific and general (for classes of compounds) absorption factors that have been found in the limited database available. The factors were compiled from existing national guidance and peer-reviewed scientific literature. It is recommended that these numbers be used as defaults for the ABS parameter when calculating RME soil exposure in the absence of chemical-specific, site-specific information. These defaults are presented in order to facilitate performance of risk assessments by compiling these factors in one place, and to promote consistency in risk assessment.

### POLYCHLORINATED BIPHENYLS (PCBs)

A review of studies assessing the dermal absorption of 3,3',4,4'-tetrachlorobiphenyl (TCB) from soil appeared in EPA, 1992. The range of absorption was reported to be 0.6% to 6%. Region III recommends accepting the 6% value as a conservative assumption of ABS for polychlorinated biphenyls, in keeping with RAGS.

## APPLICATIONS OF THIS GUIDANCE

This document represents a summary of best professional judgment at this time. It is not intended to be a detailed technical analysis of dermal exposure experimentation. As a summary of best professional judgment and default parameters, the recommendations herein may be superseded by newer, chemical-specific and route-specific studies, or by site-specific studies of acceptable quality.

These factors apply to absorption from soil or sediment. Dermal absorption of chemicals from water is discussed in RAGS and EPA, 1992.

It should be noted that when estimating absorbed doses for chemicals, dose-response parameters such as Reference Doses (RfDs) and Cancer Slope Factors (CSFs) should be adjusted accordingly, where possible and appropriate, as per RAGS Appendix A.

## SUMMARY

Dermal absorption from soil is one of the routes of exposure that may be addressed during risk assessment at Superfund sites. One factor necessary to estimate dose, and therefore risk, via this route is the absorption factor of a chemical from soil. This document recommends default assumptions for this factor in the assessment of dermal soil exposure, based on the limited available information and best professional judgment.

## REFERENCES

EPA, 1989. Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response, December, 1989. EPA/540/1-89/002.

EPA, 1992. Dermal Exposure Assessment: Principles and Applications. Interim Report. Office of Health and Environmental Assessment, January, 1992. EPA/600/8-91/011/B.

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Kao, J.K., F.K. Patterson, and J. Hall, 1985. Skin penetration and metabolism of topically applied chemicals in six mammalian species, including man: An *in vitro* study with benzo[a]pyrene and testosterone. *Toxicol. Appl. Pharmacol.* 81:502-516.

Ryan, E.A., E.T. Hawkins, et al. 1987. Assessing Risk from Dermal Exposure at Hazardous Waste Sites. In Bennett, G. and J. Bennett, eds. Superfund '87: Proceedings of the Eighth National Conference; November 16-18; Washington, D.C. The Hazardous Materials Control Research Institute. pp. 166-168.

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Wester, R.C., H.I. Maibach, et al. 1993a. *In vivo* and *in vitro* percutaneous absorption and skin decontamination of arsenic from water and soil. *Fundamental and Applied Toxicology.* Vol. 20, No. 3, pp. 336-340.

Wester, R.C., H.I. Maibach, et al. 1993b. Percutaneous absorption of pentachlorophenol from soil. *Fundamental and Applied Toxicology.* Vol. 20, No. 1, pp. 68-71.

For additional information, call (215) 597-1309.

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Region III  
Technical Guidance Manual  
Risk Assessment

## Use of Monte Carlo Simulation in Risk Assessments

EPA Contact: Dr. Roy L. Smith



EPA  
Region III

Hazardous Waste Management Division  
Office of Superfund Programs  
February 1994

EPA's current risk assessment methods express health risks as single numerical values, or "single-point" estimates of risk. This technique provides little information about uncertainty and variability surrounding the risk estimate. Recent EPA guidance (EPA, 1992) recommends developing "multiple descriptors" of risk to provide more complete information to Agency decision-makers and the public. Monte Carlo simulation is a highly effective way to produce these multiple risk descriptors. This document recommends guidelines under which Region III risk assessors may accept the optional use of Monte Carlo simulation to develop multiple descriptors of risk. *The Region will continue to require single-point risk estimates, prepared under current national guidance, in conjunction with optional Monte Carlo simulations.*

### SINGLE RISK ESTIMATES VS. MULTIPLE DESCRIPTORS

EPA designed its human health risk assessment guidance (e.g., EPA, 1991, 1989 and 1988) to produce protective, rather than best, estimates of risk. EPA is aware that true risks are probably less than its estimates, but has chosen a regulatory policy of giving the benefit of uncertainty surrounding the risk assessment to the exposed public.

These protective risk estimates sometimes create difficulty for Agency decision-makers and the public. Site-specific Regional risk assessments usually present risk as a single number, or single-point estimate, accompanied by a qualitative discussion of uncertainty. The public tends to focus on the single-point estimate and to overlook the uncertainty, which may span several orders of magnitude. EPA risk managers, though aware of the uncertainty, must still justify their decision to either accept or reduce the single-point risk. If the risk is close to the maximum acceptable level, it is likely that different assumptions would have produced a different risk number, leading to a different decision. In this way, single-point risk assessment methods place the risk assessor in an inappropriate risk management role.

Recent EPA guidance on risk characterization (EPA, 1992) discusses this problem in depth, and recommends the use of multiple risk descriptors in addition to protective single-point risk estimates. Inclusion of these additional risk descriptors provides the public with more complete information on the likelihood of various risk levels, and risk managers with multiple risk-based cleanup goals from which to choose. This guidance mentions Monte Carlo simulation as an effective source of multiple risk descriptors.

### MONTE CARLO SIMULATION

Monte Carlo simulation is a statistical technique by which a quantity is calculated repeatedly, using randomly selected "what-if" scenarios for each calculation. Though the simulation process is internally complex, commercial computer software performs the calculations as a single operation, presenting results in simple graphs and tables. These results approximate the full range of possible outcomes, and the likelihood of each. When Monte Carlo simulation is applied to risk assessment, risk appears as a frequency distribution graph similar to the familiar bell-shaped curve, which non-statisticians can understand intuitively.

Monte Carlo simulation also has important limitations, which have restrained EPA from accepting it as a preferred risk assessment tool:

1. Available software cannot distinguish between variability and uncertainty. Some factors, such as body weight and tap water ingestion, show well-described differences among individuals. These differences are called "variability". Other factors, such as frequency and duration of trespassing, are simply unknown. This lack of knowledge is called "uncertainty". Current Monte Carlo software treats uncertainty as if it were variability, which may produce misleading results.
2. Ignoring correlations among exposure variables can bias Monte Carlo calculations. However, information on possible correlations is seldom available.
3. Exposure factors developed from short-term studies with large populations may not accurately represent long-term conditions in small populations.
4. The tails of Monte Carlo risk distributions, which are of greatest regulatory interest, are very sensitive to the shape of the input distributions.

Because of these limitations, Region III does not recommend Monte Carlo simulation as the sole, or even primary, risk assessment method. Nevertheless, Monte Carlo simulation is clearly superior to the qualitative procedures currently used to analyze uncertainty and variability. For baseline risk assessments at NPL sites, Region III recommends that uncertainty and variability surrounding single-point risk estimates rely on multiple descriptors of risk (EPA, 1992). Monte Carlo simulation will be an acceptable method for developing these multiple descriptors.

The following example (from Smith, in press) illustrates the advantages of Monte Carlo simulation in risk assessment:

At a Superfund site in Region III, volatile organic compounds migrated to residential wells. The single-point RME estimate of lifetime cancer risk to exposed residents, based on ingestion of tap water and inhalation while showering, was  $1.14 \times 10^{-3}$ .

Figure 1 shows the output of a PC-based Monte Carlo simulation program for the risk assessment. Each exposure parameter was entered as a frequency distribution (i.e., a "bell-shaped" curve showing the range of possible values, and the likelihood of each)

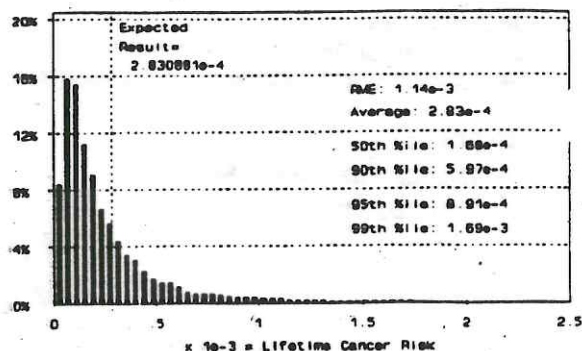


Fig 1. Probability distribution of upper bound lifetime cancer risk.

rather than as a single number. Carcinogenic potency slopes were entered as fixed values rather than frequency distributions, so the variability in risk was due entirely to the exposure assumptions.

Risk was calculated 5000 times, with each calculation based on a different randomly-selected exposure scenario. The figure lists the RME, average, and four percentiles of risk, and shows the entire risk distribution. The RME risk estimate fell between the 95th and 99th percentiles in this example, appropriately protective as intended. This figure clearly provides more complete risk information than the single numerical RME estimate.

#### GUIDELINES FOR USING MONTE CARLO SIMULAT.

Region III risk assessors believe that Monte Carlo simulation requires more development before it can serve as the primary risk assessment method, for reasons described above. However, the technique has clear advantages over the qualitative analyses of uncertainty and variability currently in use. Region III will accept Monte Carlo simulations submitted as uncertainty/variability analyses in risk assessments, under the following guidelines:

1. Include only human receptors. This guidance excludes environmental receptors.
2. Submit a work plan for EPA review before doing the Monte Carlo simulation, to ensure the work will be acceptable to EPA. The workplan should describe the software to be used, the exposure routes and models, and input probability distributions and their sources. EPA expects that peer-reviewed literature and site-specific data will be used whenever possible. Use professional judgment only as a last resort, and only in the form of triangular or uniform distributions. Describe correlations among input variables will be han

## CHLORINATED DIOXINS

A review of studies assessing the dermal absorption of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) from soil appeared in EPA, 1992. The range of absorption was reported to be 0.1% to 3%. Region III recommends accepting the 3% value as a conservative assumption of ABS for chlorinated dioxins, in keeping with RAGS.

## CADMIUM

A review of studies assessing the dermal absorption of cadmium from soil appeared in EPA, 1992. The range of absorption was reported to be 0.1% to 1%. Region III recommends accepting the 1% value as a conservative assumption of ABS for cadmium, in keeping with RAGS.

## ARSENIC

In vivo studies from Wester *et al.*, 1993a, report 3.2% for a dose of 0.6 ug/cm<sup>2</sup>. Region III recommends accepting this as a default ABS for arsenic.

## OTHER METALS

Suggested ABS factors based on the pharmacokinetic properties of chemicals appeared in Ryan *et al.*, 1987. The proposed range for dermal absorption of inorganics from soil was 0.1% to 1%. This was also consistent with a review of the studies for cadmium, an inorganic, as assessed in EPA, 1992. Region III recommends accepting the 1% value as a conservative assumption of ABS for inorganics, in keeping with RAGS.

## VOLATILE ORGANIC COMPOUNDS

Volatile organics are especially difficult to assess, because most studies to date have involved occluding the skin, which may give artificially high ABS values, since these compounds would also be expected to volatilize from the skin. Suggested ABS factors based on the pharmacokinetic properties of chemicals appeared in Ryan *et al.*, 1987. The proposed range for dermal absorption of volatile organics from soil was 10% to 25%. However, experimental data show even lower ABS values for volatile organics. For volatile organics such as benzene (vapor pressure approximately 95.2 mm Hg), Region III recommends accepting the 0.05% value based on Skowronski *et al.*, 1988, and Franz, 1984. This would include chemicals such as 1,1-dichloroethane, 1,1,1-trichloroethane, and other volatiles with vapor pressure similar to or greater

than that of benzene. For volatiles such as ethylbenzene, tetrachloroethene, toluene, and xylenes, which have vapor pressures lower than that of benzene (and less volatilization from the skin may occur), a default ABS of 3% is recommended.

These numbers only apply to non-occluded skin, which would be the scenario expected for most environmental exposures. If, however, the skin is occluded for any reason, higher ABS values (up to 100%) should be used.

## PENTACHLOROPHENOL

In vivo studies from Wester *et al.*, 1993b, report 24.4% for a dose of 0.7 ug/cm<sup>2</sup> in soil. Region III recommends accepting this as a default ABS for pentachlorophenol.

## OTHER SEMIVOLATILE ORGANIC COMPOUNDS

Suggested ABS factors based on the pharmacokinetic properties of chemicals appeared in Ryan *et al.*, 1987. The proposed range for dermal absorption of semivolatile organics from soil was 1% to 10%. The reported absorption of topically applied pure benzo[a]pyrene in studies in EPA, 1992, ranged from 1% to 13%. Kao *et al.*, 1985, reported approximately 3% for absorption of topically applied pure benzo[a]pyrene by *in vitro* human skin. The absorption from soil would be expected to be lower and indicates that the range in Ryan *et al.*, 1987, may be conservative with respect to this particular compound but not necessarily unreasonable. Region III recommends accepting the 10% value as a conservative assumption of ABS for semivolatile organics, in keeping with RAGS.

## PESTICIDES

Suggested ABS factors based on the pharmacokinetic properties of chemicals appeared in Ryan *et al.*, 1987. The proposed range for dermal absorption of pesticides from soil was 1% to 10%. The reported absorption of topically applied pesticides and herbicides in acetone to *in vitro* human skin was reported to be within this range for lindane, aldrin, dieldrin, malathion, parathion, and 2,4-D in Feldmann and Maibach, 1974. DDT absorption from soil in monkey and human skin was reported to range from 1.04 to 3.3% in EPA, 1992. These studies indicate that the range in Ryan *et al.*, 1987, may be conservative but not necessarily unreasonable. Region III recommends accepting the 10% value as a conservative assumption of ABS for pesticides, in keeping with RAGS.

3. Include only exposure variables in the Monte Carlo simulation. Enter reference doses and carcinogenic slope factors as single numbers, except for specific contaminants for which the EPA Office of Research and Development has already approved frequency distributions.
4. Include only significant exposure scenarios and contaminants in the Monte Carlo simulation. First, calculate RME risks for all exposure routes under current guidance. Select exposure routes for which RME risk exceeds either  $1\text{e-}6$  cancer risk or a non-carcinogenic hazard index of 1. Include only contaminants which contribute 1% or more of the total RME risk or hazard index.
5. Use Monte Carlo simulation only to analyze uncertainty and variability, as a "multiple descriptor" of risk. Include standard RME risk estimates in all graphs and tables of Monte Carlo results. Generate deterministic risks using current EPA national guidance (EPA 1992, 1991, 1989, and 1988).
6. Include graphs and tables showing and describing each input distribution, distributions of risk for each exposure route, and distributions of total risk (summed across exposure pathways and age groups, as appropriate under current guidance).

Region III will not accept Monte Carlo simulations which are not approved beforehand, or do not adhere to these guidelines.

#### SUMMARY

Region III will accept Monte Carlo simulations that conform to the guidelines in this document, as part of baseline human health risk assessments. The most important guideline is that all risk assessments must include single-point RME risk estimates prepared under current EPA national guidance. The Region will accept Monte Carlo simulation only as an optional addition to, not a substitute for, current risk assessment methods.

#### REFERENCES

EPA, 1992. Guidance on Risk Characterization for Risk Managers and Risk Assessors, (U.S. Environmental Protection Agency, Office of the Administrator, Washington, DC, memorandum from F. Henry Habicht on 26 February 1992).

EPA, 1991. Standard Default Exposure Factors, *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual Supplemental Guidance*, (U.S. Environmental Protection Agency

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Smith, R.L. In press. Use of Monte Carlo simulation for human exposure at a Superfund site. Submitted to *Risk Analysis*, May 1993.

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